

REMARKS

Claims 124-140 are pending in the application. Claims 128-134 are withdrawn by the examiner. Claims 124-127 and 135-140 are currently under examination. Claims 124, 126, and 127 are amended to clarify that the method step of "quenching residual free radicals in the crosslinked UHMWPE" is carried out "by heating the irradiated UHMWPE". Support for the amendment can be found throughout the specification (for example, see page 19). Claims 138-140 are amended by deleting the decimal point, as clarified herein. Therefore, no new matter is introduced. The office action is discussed below:

Written Description Rejection:

On pages 5-7 of the Office Action, the examiner rejects claims 124-127 and 135-140 under 35 U.S.C. 112, first paragraph, allegedly for failing to comply with the written description requirement.

Regarding claims 124-127, the examiner asserts while applicant teaches pre-heating, the examiner has not found any disclosure of pre-heating "at a temperature greater than ambient temperature and less than the decomposition temperature" or "for a period of time greater than about 30 minutes". Applicants disagree with the examiner and submit that the examiner's intention to limit claims to certain embodiments of the specification, for example, the MIR method of heating above the melting temperature of UHMWPE for a time period "for about 30 minutes to about 2 hours" before irradiation and cooled to about 25°C after irradiation (such as described in pages 29-31), or any other alternative, such as "preheating to a temperature below the melting temperature of the UHMWPE", irradiation of the UHMWPE, followed by heating to a temperature above the melting temperature for a time period of about 0.5 minutes to about 24 hours, preferably about 1 hour to about 3 hours and most preferably for 2 hours so there are no detectable free radicals in the CIR or WIR method (such as described in pages 21-24), is not appropriate. Regarding the term "ambient temperature", applicants point out that the specification refers to "room temperature", which essentially refers to the same environment. Applicants refer the examiner to Wikipedia dictionary for a definition of

the terms. "*Room temperature* implies a temperature inside a temperature-controlled building. *Ambient temperature* simply means "the temperature of the surroundings" and will be the same as room temperature indoors" (http://en.wikipedia.org/wiki/Room_temperature).

The examiner contends that there is no disclosure to support the instant claim recitation "quenching residual free radicals" after pre-heating and irradiation. However, the examiner admits that the specification discloses a cooling step after irradiation and that the disclosed method provides "crosslinked UHMWPE having substantially no detectable free radicals". Applicants point out that claims are interpreted in view of the specification and one skilled in the art would appreciate the disclosure of various methods of reducing (quenching) residual free radicals. Claims clearly recite "quenching residual free radicals" after pre-heating and irradiation steps.

The examiner states that the method disclosed for obtaining "crosslinked UHMWPE having substantially no detectable free radicals" requires heating the irradiated UHMWPE after irradiation to above the melting temperature of UHMWPE (referred to specification pages 14, 20 and 21). Applicants point out that the specification, for example page 14, clearly describes "The free radicals can be eliminated by any method which gives this result, e.g., by heating the UHMWPE above its melting point such that substantially no residual crystalline structure remains." Although various process of heating is described throughout the specification, the examiner is trying to limit the claims to certain embodiments, for example, a process of heating above the melting point. This is not permissible. In this context, applicants request the examiner to consider the MPEP § 2111 that:

"The Patent and Trademark Office ("PTO") determines the scope of claims in patent applications not solely on the basis of the claim language, but upon giving claims their broadest reasonable construction "in light of the specification as it would be interpreted by one of ordinary skill in the art." *In re Am. Acad. of Sci. Tech. Ctr.*, 367 F.3d 1359, 1364, [70 USPQ2d 1827] (Fed. Cir. 2004)."

With respect to claim 125, the examiner also could not find any disclosure of the recited cooling after the quenching step "to a temperature below the melting temperature of the polyethylene". The examiner states, what is disclosed is cooling to

room temperature after the step of heating irradiated UHMWPE to above the melting temperature to provide "substantially no detectable free radicals". Apparently, the examiner did not consider that the quenching step involves heating, which provides polymeric materials having "substantially no detectable free radicals". Again, the examiner is trying to limit the claims to certain embodiment of the specification (such as described at page 18), which is not permissible. Applicants point out that the specification at page 18 discloses cooling step after heating irradiated UHMWPE.

Applicants submit that the examiner's interpretation of the claims 124-127 in view of certain aspects of the specification (such as pages 14, 20 and 21) and to limiting the claims to those aspects of the invention is not permissible. In this context, applicants also request the examiner to consider the MPEP that:

Claim terms are to be given their plain meaning as understood by the person of ordinary skill in the art, particularly given the limitations of the English language. See MPEP §§ 707.07(g); 2111.01 (Rev. 6, September 2007).

Claims must be "given their broadest reasonable interpretation consistent with the specification." See the Federal Circuit's *en banc* decision in *Phillips v. AWH Corp.*, 415 F.3d 1303, 75 USPQ2d 1321 (Fed. Cir. 2005); *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed Cir. 1989) (holding that claims must be interpreted as broadly as their terms reasonably allow). See also MPEP § 2111 (Rev. 6, September 2007).

With respect to claims 135-137, the examiner states that a step for obtaining "substantially no free radicals" is disclosed in the specification on pages 14 and 21-22, wherein methods including the instantly claimed pre-heating are disclosed, i.e. "CIR" and "WIR" methods, which requires heating the irradiated UHMWPE above the melting temperature of the UHMWPE.

The examiner states that there is no disclosure of the recited heating the irradiated UHMWPE preform to a temperature "above ambient temperature" to "quench" free radicals or of a "quenching step". Applicants refer the examiner to above clarification of the terms, such as ambient vs. room temperature. The examiner admits that the instant specification discloses a method wherein, subsequent to irradiation, the irradiated UHMWPE is heated to yield a product having substantially no free radicals. The examiner opines that the method disclosed should be clearly set forth in the instant

claims. Applicants believe, claims recite all required steps for one skilled in the art to be able to practice the invention in view of the specification, and are as clear as issued U.S. Patent No. 6,562,540, from which the claims were originally based. However, without acquiescing in the rejection, in order to expedite the prosecution, applicants amend the claims to clarify that the method step of "quenching residual free radicals in the crosslinked UHMWPE" is carried out "by heating the irradiated UHMWPE".

With respect to claims 138-140, the examiner asserts that the disclosure in the specification is that the UHMWPE preform is irradiated at a dose of "about 4 Mrads to about 30 Mrads", not at a dose of "about 4.0 Mrads to about 30 Mrads" as set forth in the claims (refers to page 19 of the specification). Applicants disagree with the examiner and point out that page 19 also discloses radiation dose to a decimal point of 0.05 Mrad/minute, *per se*, which inherently can result in a dose of "about 4.0 Mrads to about 30.0 Mrads". However, in order to expedite the prosecution, applicants amend the claims by deleting the decimal points.

In view of the above clarifications and amendments to the claims, applicants request withdrawal of the written description rejection.

Enablement Rejection:

On page 7 of the Office Action, the examiner rejects claims 124-127 under 35 U.S.C. 112, first paragraph, allegedly as based on a disclosure which is not enabling. According to the examiner, heating irradiated UHMWPE above the melting temperature of the UHMWPE during the quenching of residual free radicals step discloses as being critical or essential to the practice of the invention, is not included in the claim(s). Thus, the examiner believes that claims, as written, are not enabled by the disclosure. The examiner opines that the disclosure of "quenching residual free radicals" after pre-heating and irradiation in the instant specification requires heating above the melting temperature of UHMWPE. Applicants disagree with the examiner and clarify as above that the quenching step involves heating as disclosed in the specification. In addition, applicants amend the claims to clarify that "quenching residual free radicals in the crosslinked UHMWPE" is carried out "by heating the

irradiated UHMWPE", as discussed above. Accordingly, withdrawal of the enablement rejection is solicited.

Rejections Maintained & Response to Arguments:

Anticipation Rejection:

On pages 2-4 and 7-8 of the Office Action, the examiner has maintained the alleged anticipation rejection of claims 124-127 in view of Shalaby (the '411 patent).

On page 2 of the Office Action, the examiner alleges that claim language does not set forth any specific steps for "quenching residual free radicals", thus reads on chemical methods for quenching free radicals. The examiner also alleges that the claim language does not specify the kind of irradiation or irradiation dose applied to the UHMWPE perform. The examiner believes that Shalaby *et al.* teach that exposure to high energy radiation results in crosslinking and further that crosslinking is enhanced upon irradiation in an acetylene environment.

Applicants respectfully disagree with the examiner and submit that Shalaby mentions about "high energy radiation", which refers to sterilization dose of 2.50 Mrads, which is a "low dose irradiation" or "sterilization irradiation." More specifically, Shalaby discloses "a dose of 2.50 Mrads in three different gas environments, namely, air, nitrogen (practically pure), and acetylene" (see Shalaby Example 5, also see Example 7 and Figure 6). Such "low dose irradiation" or "sterilization irradiation" would generate residual free radicals and would not be "quenching residual free radicals in the ultrahigh molecular weight polyethylene preform subsequent to the irradiating step", as required by the claimed method. Applicants point out that the examiner has not provided any support based on Shalaby's disclosure where "high energy radiation" is referred as any other process but a sterilization process.

However, without acquiescing in the examiner's rejection, in order to advance the prosecution, applicants amend claims 124, 126, and 127 to clarify that "quenching residual free radicals in the crosslinked UHMWPE" is carried out "by heating the irradiated UHMWPE". The amendment further distinguishes the claimed invention from

the cited reference that the residual free radicals are quenched by heating the irradiated UHMWPE. Consequently, Shalaby does not anticipate the claimed invention. Withdrawal of the anticipation rejection is therefore solicited.

Obviousness Rejection:

On pages 4 and 8-9 of the Office Action, the examiner has maintained the alleged obviousness rejection of claims 124-127 and 135-137 in view of Sun (the '049 patent). Again, applicants disagree with the examiner and submit, as discussed above, that the "low dose irradiation" or "sterilization irradiation" of Sun would generate residual free radicals and would not be quenching residual free radicals in the crosslinked ultrahigh molecular weight polyethylene preform subsequent to the irradiating step, as required by the claimed method.

Applicants note, the examiner has admitted on page 8 of the Office Action that Sun describes radiation sterilization of implants and does not teach treating polyethylene preform as required by the claimed invention.

Applicants point out that the independent claims, as amended, further clarifies the manner of quenching of irradiated UHMWPE preform. Quenching residual free radicals in the UHMWPE preform subsequent to the irradiation crosslinking step is nowhere suggested in Sun disclosure. Also, Sun provides no motivation or suggestion to one of ordinary skill in the art, at the time of the invention, to quench residual free radicals by treating a crosslinked UHMWPE preform subsequent to the irradiation crosslinking step, as required by the claimed methods. Therefore, Sun does not make the claimed methods obvious. Accordingly, withdrawal of the obviousness rejection is solicited.

Double Patenting Rejections:

On pages 4 and 9-11 of the Office Action, the examiner also has maintained the provisional rejection of claims 124-127 and newly rejected claims 135-140 under the judicially created doctrine of obviousness-type double patenting allegedly as being

unpatentable over various pending claims of co-pending applications serial nos. 10/948,440, 10/197,209, 10/696,362, 10/901,089 and 10/197,263.

Applicants remind the examiner that none of the cited co-pending applications have received a notice of allowance. Therefore, the merits of this provisional rejection need not be discussed at this time (*see* MPEP § 822.01).

Examiner's Comments in Conclusion:

On page 12 of the Office Action, the examiner asserts that Shen *et al.* (US 6,228,900) disclose a method comprising irradiation of an UHMWPE preform with from 1 to 100 Mrad and annealing or remelting the irradiated UHMWPE. The examiner admits that Shen *et al.* do not mention pre-heating the UHMWPE preform before irradiating the preform. However, the examiner interprets that the instant claims do not clearly set forth the sequence in which the recited "pre-heating" and "irradiating" and "quenching" take place, or whether the irradiating is performed on the preform while heated or after pre-heating and cooling to room temperature, for example. Applicants disagree with the examiner and point out that claimed method steps clearly recite "pre-heating", "irradiating" and "quenching" in a sequential manner. It is further clear from the amendment to the independent claims and above clarifications that the claimed methods require sequentially quenching of residual free radicals by heating a crosslinked UHMWPE preform subsequent to the irradiation crosslinking step. The term 'pre-heating' itself clarifies a heating step prior to any other treatment of the UHMWPE preform. Therefore, the instant claims do clearly set forth the sequence in which the recited "pre-heating" and "irradiating" and "quenching" take place.

REQUEST


Applicants submit that claims 124-127 and 135-140 are in condition for allowance, and respectfully request favorable consideration to that effect. The examiner is invited to contact the undersigned at (202) 434-1610 should there be any questions.

Respectfully submitted,

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